K120811

Utfärdare/*Issuer*	Ref nr/Dok nr/*Ref no/Doc no*	Utgåva /*Edition*
Viveka Wretman	--	--
Avser/*Regarding*		Directory
Leksell Gamma Knife Perfexion		--

Section 4- 510(k) Summary

As Required by 21 CFR 807.87(k)510 (k) Summary

1. *Subscribers Name & Address*

Elekta Instrument AB
Kungstensgatan 18, P.O. Box 7593
SE-103 93 Stockholm, Sweden
Tel: (011) 46 8 587 254 00
Fax: (011) 46 8 587 255 00
Official Correspondent: Mr Anders Skoglund

MAY 2 4 2012

2. *Trade Name*

Leksell Gamma Knife® Perfexion™

3. *Device Classification*

Common Name	Product Code	Class	Regulation Number
Leksell Gamma Knife® Perfexion™	IWB	II	21 CFR 892.5750

4. *Predicate Device Identification*

Legally marketed devices to which equivalence is being claimed	510(k) #
Leksell Gamma Knife® Perfexion™	K063512

5. *Other relevant submissions*

Devices	510(k) #
Leksell Steretocatic System	K080355
Leksell GammaPlan® PFX	K103093

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6. *Device Description*

Leksell Gamma Knife Perfexion is a radiosurgery system for use in the stereotactic irradiation of intra-cranial structures. Surgery is achieved by delivering a prescribed dose as one or more shots of ionizing radiation to the exact site of the target.

Based on preoperative radiological examinations, the Leksell Gamma Knife Perfexion unit provides highly accurate external irradiation of intra-cranial structures using collimated beams of ionizing radiation.

Each unit contains 192 sealed sources of Cobalt 60.

Leksell Gamma Knife Perfexion systems consists of several units, physically separated in an Office side in the control room and a Medical side in the treatment room.

- The medical side consists basically of the radiation unit with a patient positioning system. The system control and power units are placed inside the cover of the radiation unit.
- The office side consists of the operator console with control panel and office computer.

7. *Intended Use*

Leksell Gamma Knife® Perfexion is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g. metastatic tumors, arteriovenous malformations, trigeminal neuralgia, meningiomas and vestibular schwannomas.

8 *Substantial Equivalence*

The functionality for the Leksell Gamma Knife Perfexion is equivalent to its predicate device K063512 in safety and effectiveness. The fundamental technical characteristics are the same to those of the predicate device and are listed on the comparison charts provided in this 510 (k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Viveka Wretman
Regulatory Affairs Engineer
Elekta Instrument AB
Kungstensgatan 18
STOCKHOLM 10393
SWEDEN

MAY 24 2012

Re: K120811
Trade/Device Name: Leksell Gamma Knife Perfexion
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: March 14, 2012
Received: March 16, 2012

Dear Ms. Wretman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ELEKTA INSTRUMENT AB

Dokumentnamn/*Name of document*
Traditional 510(k) K120811[18]

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Section 7- Indications for Use Statement

510(k) Number	To be defined
Device Name	Leksell Gamma Knife Perfexion
Indications for Use	Leksell Gamma Knife® Perfexion is a teletherapy device intended for stereotactic irradiation of head structures ranging from very small target sizes of a few millimeters to several centimeters e.g. metastatic tumors, arteriovenous malformations, trigeminal neuralgia, meningiomas and vestibular schwannomas.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120811